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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,667	12/03/2001	Esteban Masuda	021044-000600US	7585

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EXAMINER	
HUTSON, RICHARD G	
ART UNIT	**PAPER NUMBER**
1652	

MAIL DATE	DELIVERY MODE
11/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/998,667	MASUDA ET AL.	
	Examiner	Art Unit	
	Richard G. Hutson	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,6 and 9-50* is/are pending in the application.

4a) Of the above claim(s) *17,18 and 20-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,6,9-16,19 and 47-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/16/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment of claims 1, 6 and 22 and the cancellation of claims 3-5, 7 and 8,and the addition of new claims 48-50 in the paper of 8/16/2007, are acknowledged. Claims 1, 2, 6, 9-50 are still at issue and are present for examination.

Applicants' arguments filed on 8/16/2007, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claims 17, 18, 20-46 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 6, 9-16, 19 and 47-50 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection is stated in the previous office action as it applies to previous claims 1, 2, 6, 9-16, 19 and 47. In response to this rejection, applicants have amended

claims 1, 6 and 22, cancelled claims 3-5, 7 and 8,and added new claims 48-50 and traverse the rejection as it applies to the newly amended claims.

Applicants traverse this rejection on the basis that applicants have amended claim 1 to recite, in part, "wherein the TRAC 1 polypeptide has ubiquitin ligase activity" and Applicants submit that by virtue of this amendment, a sufficient functional limitation has been placed on the ligase activity of the present invention. Applicants submit that the recitation of this further functional limitation would allow the skilled artisan to recognize that the Applicants are in possession of the claimed invention.

Applicants further point to the decision by the Board of Patent Appeals and Interferences, Ex parte Sun, Appeal No. 2003-1993 and submit that the facts in Ex Parte Sun closely mirror those in the present case, and thus, under the standard used by the Board in Sun, the claims of the present invention satisfy the written description requirement. In the present case, the sequence of a particular TRAC 1 polypeptide is provided as a reference sequence (SEQ ID NO: 1), a per cent identity to that reference sequence is claimed, and functional assays for the genus of ubiquitin ligase enzymes are well known in the art, such as those disclosed in WO 01/75145, incorporated by reference in the present application. Thus, applicants submit that under the standard set forth in *Sun*, the claims of the present invention are supported by adequate written description in the specification.

Applicant's amendment of the claims and applicants complete argument continues to be acknowledged and has been carefully considered, however continues to be found nonpersuasive for the reasons previously stated and repeated herein.

While applicants amendment requiring a more specific functional limitation of the claimed genus of TRAC1 polypeptides is acknowledged, a sufficient structure to function relationship has not been established to meet the requirements of the written description guidelines, because applicants amendment requiring that the claimed genus of TRAC1 polypeptides have "ubiquitin ligase activity" in combination with an amino acid sequence having a mere 90% identity to SEQ ID NO: 1, is not a sufficient structure to functional description of the claimed methods, such that the skilled artisan would not recognize that applicants were in possession of a majority of the members of the claimed genus by virtue of this broad functional description.

Applicants comments regarding the decision by the Board of Patent Appeals and Interferences, Ex parte Sun, Appeal No. 2003-1993 is acknowledged, however, more than the sequence of a particular TRAC 1 polypeptide, a percent identity to the reference sequence and a functional assay for the genus is necessary to adequately describe the genus of claimed methods. Applicants are reminded that applicant's claims are to a genus of methods for identifying a compound that modulates T lymphocyte activation and it is this genus of methods that need adequate description. Applicants complete amendment and arguments continue to be acknowledged, however, are not found persuasive in meeting that which is needed to adequately describe the claimed genus of methods.

Given the lack of additional representative species as encompassed by the claims, Applicants continue to have failed to sufficiently describe the claimed invention,

in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 1, 2, 6, 9-16, 19 and 47-50 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method comprising contacting a compound (any small organic) with a TRAC1 polypeptide, wherein said TRAC1 polypeptide comprises the amino acid sequence of SEQ ID NO: 1 and determining the functional effect of the compound upon the TRAC1 polypeptide, does not reasonably provide enablement for any method comprising contacting a compound (any small organic) with any TRAC1 polypeptide comprising an amino acid sequence having at least 90% identity to the amino acid sequence of SEQ ID NO: 1, having any ligase activity and determining any functional effect of the compound upon the TRAC1 polypeptide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The rejection is stated in the previous office action as it applies to previous claims 1, 2, 6, 9-16, 19 and 47. In response to this rejection, applicants have amended claims 1, 6 and 22, cancelled claims 3-5, 7 and 8,and added new claims 48-50 and traverse the rejection as it applies to the newly amended claims

Applicants traverse this rejection as above, on the basis those applicants have amended claim 1 to recite, in part, "wherein the TRAC 1 polypeptide has ubiquitin ligase activity" and Applicants submit that by virtue of this amendment, a sufficient functional limitation has been placed on the ligase activity of the present invention. Applicants submit that the recitation of this further functional limitation would allow the skilled artisan to recognize that the Applicants are in possession of the claimed invention. Applicants further submit that the claimed invention relies on the use of a TRAC 1 polypeptide (SEQ ID NO: 1) and variants that have at least about 90% or greater identity to SEQ ID NO: 1, wherein the TRAC 1 polypeptide has ubiquitin ligase activity. Applicants submit that thus, in order to practice the claimed method, the skilled artisan needs to have (1) access to a nucleic acid encoding TRAC 1; (2) knowledge of how to alter the amino acid sequence of EDG-1 so that it is 90% - 99.9% identical to SEQ ID NO: 1; (3) methods for expressing and testing the activity of TRAC1 polypeptides that are 90% - 100% identical to SEQ ID NO: 1 either in vitro or in vivo; and (4) assays for determining the functional effect of test compounds on TRAC 1 polypeptide activity. The specification and common knowledge in the art provides ample guidance that renders each of these steps easily performed by a skilled artisan in the fields of molecular biology and cell biology, such that no more than routine experimentation is required to practice the claimed invention. Applicants submit that they disclose 1) the cDNA sequence of TRAC1 as SEQ ID NO:I; and (2) methods of isolating TRAC 1 orthologs, variants, polymorphic variants, and conservatively modified variants that are at least about 90% identical to SEQ ID NO: 1 are well know in the art of molecular biology and

are disclosed in the specification, (3) methods for the expression of TRAC 1 polypeptides are also well known in the arts of molecular and cell biology and biochemistry and are disclosed in the specification; assays for ubiquitin ligase activity of TRAC1 are disclosed in the specification and (4) assays for identifying modulators of TRAC 1 polypeptides are disclosed in the specification. Thus applicants submit that they have enabled the claims as amended.

As above, applicant's amendment of the claims and applicants complete argument is acknowledged and has been carefully considered, however, continues to be found nonpersuasive for the reasons previously stated and repeated herein. While applicants amendment requiring additional structure of the claimed genus of TRAC1 polypeptides is acknowledged, a sufficient structure to function relationship has not been established to enable the scope of applicants claimed invention, because applicants amendment requiring that the claimed genus of TRAC1 polypeptides have "ubiquitin ligase activity" is not a sufficient functional limitation of the claimed method, such that the skilled artisan would require undue experimentation to practice the methods of the claimed genus by virtue of this broad functional description.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any method comprising contacting a compound with any "any TRAC1 polypeptide comprising an amino acid sequence having at least 90% identity to the amino acid sequence of SEQ ID NO: 1 and having any ubiquitin ligase activity, wherein said method involves determining any functional

effect upon the TRAC1 polypeptide" and determining the functional effect of the compound upon the TRAC1 polypeptide. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of those methods of use of those TRAC1 polypeptides, having the desired biological characteristics, is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 13, 15, 16, 19 and 47 are rejected under 35 U.S.C. 102(a) as being anticipated by Sitkovsky (U.S. Patent No. 5,180,662).

The rejection is stated in the previous office action as it applies to previous claims 1, 2, 13, 15, 16, 19 and 47. In response to this rejection, applicants have amended claims 1, 6 and 22, cancelled claims 3-5, 7 and 8,and added new claims 48-50 and traverse the rejection as it applies to the newly amended claims.

Applicants argue this rejection on the basis that applicants have amended claim 1 to recite "contacting the compound with a recombinant TRAC1 polypeptide" and

Sitkovsky et al. does not teach or suggest a recombinant TRAC1 polypeptide as recited in amended claim 1. Applicants submit that because Sitkovsky et al. does not teach or suggest each and every element of amended claim 1 as required to anticipate the claimed invention, the rejection should be withdrawn.

Applicant's amendment and complete argument is acknowledged and has been carefully considered, however continues to be found nonpersuasive for the reasons previously made of record and for those repeated herein.

With respect to applicants comments that claim 1 has been amended to recite "contacting the compound with a recombinant TRAC1 polypeptide" and Sitkovsky et al. does not teach or suggest a recombinant TRAC1 polypeptide as recited in amended claim 1, applicants are reminded that Sitkovsky et al. teaches each and all of the active method steps of the claims and the only difference between the claimed method and that taught by Sitkovsky et al., according to applicants, that applicants TRAC1 polypeptide is recombinant and that the TRAC1 polypeptide of Sitkovsky et al. is at best "a native TRAC1 polypeptide". Applicants argument is not found persuasive on the basis that applicant's argument that the TRAC1 polypeptide of the claims is recombinant is interpreted as a "process of making" type of limitation and there is no difference between a TRAC1 polypeptide which is expressed either natively or by recombinant means. Regardless of how one would describe the TRAC1 polypeptide of the claimed method, the claimed method steps are the same and the method taught by Sitkovsky et al. anticipates the claims.

Thus claims 1, 2, 13, 15, 16, 19 and 47 remain anticipated by Sitkovsky for the reasons previously stated and repeated herein.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is 571-272-0930. The examiner can normally be reached on M-F, 7:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax

phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Richard G Hutson, Ph.D.
Primary Examiner
Art Unit 1652

rgh
10/30/2007